

REMARKS

On February 25, 2008, Applicants filed a response to the Restriction Requirement mailed on January 24, 2008. In that response, the Applicants provisionally elected with traverse the claims of Group I (claims 1-16 and 18) for prosecution.

In response to the instant Communication mailed June 6, the Applicants provisionally elect "the absence of additional components."

While not conceding the propriety of any aspect of the restriction requirement, Applicants make this election provisionally with traverse, and for the sole purpose of advancing the application in the examination process. In this regard, Applicants wish to note that restriction is not "required" by 35 U.S.C. §121 as implied by the Examiner. Congress wisely gave the Commissioner administratively constrained "discretion" to impose restriction, when appropriate. According to 35 U.S.C. § 121 "... the Commissioner may require claims in an application to be restricted...." (emphasis added). In other words, the Commissioner is not required to restrict claims in an application. Likewise, the MPEP § 803 lists two criteria that must be present for restriction between alleged claim groups to be proper:

- 1) The invention in allegedly "restrictable" or "separable" claim groups must be independent or distinct; and
- 2) There must be a serious burden on the Examiner if restriction is not required (emphasis added).

Applicants respectfully assert that restriction is not proper or "required" here because, among other things, the Examiner has failed to establish the claims as she has grouped them are sufficiently distinct to warrant restriction or the Examiner has failed to show that there will be a serious and "undue" burden on the Examiner if the claims are examined together. It is a more efficient use of Patent Office manpower and resources to examine all claims which are closely related at one time, rather than conducting separate examinations.

In the Communication mailed January 24, 2008, the Examiner made certain assertions regarding the novelty and inventive step of the present claims. Applicants hereby traverse these assertions and, by making the present election, Applicants neither agree nor disagree with these assertions. Applicants reserve the right to fully defend the present or any other claims during prosecution on the merits with regard to any substantive rejections or with regard to other effects of these potentially untoward and unnecessary assertions.

With respect to the alleged species election requirement, Applicants likewise traverse that such a restriction is proper. The Examiner has alleged that each of the alleged additional components and combinations of additional components are independent and distinct species that are "mutually exclusive." For example, and not by way of limitation, Applicants assert that one would not necessarily consider that the alleged component "(b) isotonyfying agent" and the alleged component "(e) isotonyfying agent and one or more pharmaceutically acceptable excipient(s)" are or would be mutually exclusive, nor

would one necessarily reasonably expect that these alleged different components would require a different field of search.

Because the Examiner has not shown that the claims are sufficiently distinct or she has not shown that she would be seriously unduly burdened if she examines all the claims and/or species in one proceeding, Applicants once again respectfully submit that restriction is not proper in this case and they urge the Examiner to reconsider and withdraw the restriction requirement.

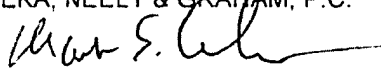
If the Examiner identifies further issues which may be resolved by telephone, the Examiner is invited to contact the undersigned at (865) 546-4305.

In the event that this response is not timely filed, Applicants hereby petition for an appropriate extension of time. The fee for this extension, along with any other fees which may be due with respect to this response, may be charged to our Deposit Account No. 12-2355.

Respectfully submitted,

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